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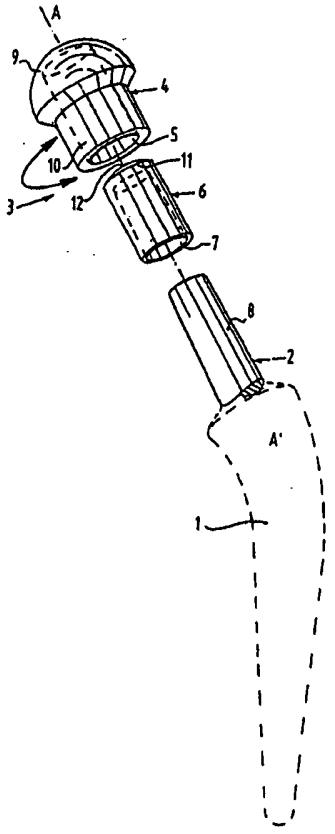
(57) Abstract

The invention relates to a coupling means (3) for a femur prosthesis (1) comprising an adaptor element (6) and a ball element (4), which elements (6, 4) are each provided with a blind central bore (7, 5), wherein the bore (7) of the adaptor elememt (6) is suitable in shape and dimension to enable placing over a fixed stem end (2) of a femur prosthesis (1) and wherein the bore (5) of the ball element (4) is suitable in shape and dimension to enable placing over the adaptor element (6), and wherein, when arranged over each other, the ball element (4) is mounted for free rotation relative to the fixed stem end (2), wherein the ball element (4) consists of a spherical ball head (9) which transposes into a substantially cylindrical ball collar (10), which ball element (4) is provided with a blind central bore (5) which extends through the whole ball collar (10) into a considerable part of the ball head (9).



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# COUPLING MEANS FOR FEMUR PROSTHESIS

The invention relates to a coupling means for a femur prosthesis comprising an adaptor element and a ball element, which elements are each provided with a blind central bore, wherein the bore of the adaptor element is suitable in shape and dimension to enable placing over a fixed stem end of a femur prosthesis and wherein the bore of the ball element is suitable in shape and dimension to in turn enable placing over the adaptor element as according to the preamble of claim 1.

Such coupling means are generally known. An example of such a coupling is disclosed in EP-A-0 147 339.

Known coupling means with adaptor elements have the feature that the ball element is arranged fixedly on the adaptor element and the adaptor element is in turn coupled fixedly to the stem end of the femur prosthesis. Both elements are generally provided for this purpose with a truncated cone-shaped bore.

Another example of such a known coupling means is described in the patent US-A-5 080 697. In the embodiments of couplings shown herein there also occur fixed connections between the adaptor element and the stem end of the femur prosthesis on the one side and between the ball element and the adaptor element on the other.

It has been found however that these fixed connections can be disadvantageous, this particularly from tests, the results of which were recently published by van der Vis et al. in Acta Orthop Scand 1998 under the title "Socket wear in ceramic-on-polyethylene total hip arthroplasties". Shown herein is a rotatably mounted coupling which also operates telescopically. The rotating coupling shown herein is however not spared considerable friction due to the large common surfaces rotating on one another and because of the material used, whereby wear soon occurs. The rotating coupling shown herein is however not provided with any adaptor element.

The object of the present invention is to provide a coupling means which on the one hand has the advantages of an adaptor element which can be adjusted for instance in axial length and which on the other hand has the advantages of a rotating coupling and which is moreover mounted for rotation which is virtually frictionless.

Another objective is to provide a coupling means with very little wear for the time period of the average age of a person. This ensures that such a coupling has to be arranged only once in the body and replacement need never have to take place.

Another objective is to provide a coupling means which is easy to manufacture and to use, which can be obtained with known techniques of drilling and milling and which allows integral manufacture of both the adaptor element and the ball element.

In order to at least partially obviate the above stated drawbacks and to achieve at least some of the above stated objectives the invention provides a coupling means as according to claim 1.

By arranging a ball element which is mounted for free rotation relative to the fixed stem end, which ball element is arranged over the adaptor element, the advantages of the use of an adaptor element as well as of the rotation can be realized.

In a preferred embodiment a coupling means according to the invention comprises a ball element, the central blind bore of which is at least partially cylindrical, and a corresponding part of the sleeve of the adaptor element has a similar cylindrical form. This has the effect that when both elements are arranged one over the other the ball element is mounted rotatably relative to the adaptor element.

In a further embodiment the coupling means is embodied such that when the ball element is mounted over the adaptor element, these two elements are in continuous mutual contact only locally at one point.

This has the effect that wear can only occur at this point. This point will generally be formed by a spherical upper surface of the adaptor element.

Other preferred embodiments of a coupling means according to the invention with such a local point contact will be elucidated hereinbelow with reference to the drawing.

The invention likewise relates to an assembly comprising a ball element and a number of adaptor elements, wherein at least two adaptor elements have a different height. By providing such a choice of different heights of adaptor elements the stem end of a femur prosthesis does not have to be shortened, while an appropriate length size can be obtained by choosing an adaptor element of a suitable height. The combined height of the stem end of the femur prosthesis and the adaptor element arranged thereover must generally correspond with the natural height of the collum femoris of the os femoris. Just as in nature the height of the collum femoris can differ in each person, different heights of adaptors are provided.

The invention will be elucidated hereinbelow with reference to the drawings, in which:

Fig. 1 shows a schematic view of a femur prosthesis with a perspective exploded view of a preferred embodiment of a coupling means according to the invention;

Fig. 2 shows a cross-sectional view of a preferred embodiment of a coupling means according to the invention;

Fig. 3, 4 and 5 show cross-sectional views of other preferred embodiments of a coupling means according to the invention; and

Fig. 6 shows a cross-sectional view of an assembly according to the invention.

A femur prosthesis 1 is bounded at the top by a stem end 2 which in the natural femur is the collum femoris. In order to realize a good seating of a femur prosthesis

in a socket or natural acetabulum (not shown) of the hip-bone, a coupling means 3 is provided on this stem end 2. The coupling means according to the invention consists of a ball element 4 provided with a blind central bore 5 and with an adaptor element 6, which adaptor element is likewise provided with a blind central bore 7. A stem end cap 8 can optionally be provided on stem end 2 of the femur prosthesis.

The ball element consists in its top part of a spherical ball head 9 which transposes into a substantially cylindrical ball collar 10. The blind bore 5 of ball element 4 is preferably cylindrical, whereby the sleeve of the adaptor element must have a corresponding cylindrical form so as to form a rotation bearing. Ball element 4 can hereby rotate freely on the central axis AA' when it is mounted over the adaptor element. Ball collar 10 will ensure an additional fitting seating of ball element 4 over the adaptor element, whereby the freedom of the ball element is reduced.

Adaptor element 6 is preferably provided with a truncated cone-shaped central bore 7. The stem end cap 8 is likewise truncated cone-shaped or cylindrical, whereby a non-rotating coupling is obtained between stem end cap 8 and adaptor element 6 when this latter has been placed on stem end 2 or stem end cap 8.

The bore 5 of ball element 4 extends through the whole ball collar 10 into a considerable part of ball head 9.

In order to minimize friction the adaptor element 6 is rounded on its top side 11, preferably arched or as in fig. 1 spherical, with a central summit 12.

When the blind bore 5 of ball element 4 is bounded by a flat surface 13 and the upper part 11 of adaptor element 6 is provided with a central summit 12, the adaptor element 6 will make only local contact at the central summit 12 with the surface 13 of the ball element when they are arranged one over the other. This is advantageous from a wear viewpoint, since wear can only

occur at this central summit 12. A suitable alloy wherein wear is further minimized is a metal alloy, in particular a cobalt chrome molybdenum alloy. Other metal alloys are likewise suitable, although a cobalt chrome molybdenum alloy has a good resistance to wear and is suitable for use in rotating bearings.

A preferred embodiment of such a suitable alloy comprises:

Chrome: 27 to 30%
Molybdenum: 5 to 7%
Nickel: 1% maximum
Iron: 0.75%
Carbon: 0.08% maximum
Manganese: 1% maximum
Silicon: 1% maximum
Cobalt: balance
Nitrogen: 2,000 ppm maximum.

Figures 3-6 show alternative embodiments of the coupling means according to the invention, wherein the ball element will likewise be in continuous contact with the adaptor element only locally at one point.

Fig. 6 shows an assembly of a plurality of adaptor elements 6 and one ball element 4. In order to achieve only local contact, it is likewise possible to provide the end face of the blind bore 5 with a summit 14 and to give the end face 11 of adaptor element 6 a flat form.

The embodiment of fig. 6 shows an assembly according to the invention and illustrates clearly the different height of the adaptor elements with the same bore 7.

The clearance between the diameter of bore 5 of ball element 6 and the outer diameter of the adaptor element is generally very small. This is particularly smaller than 0.02 mm and more preferably smaller than 0.01 mm. In preferred embodiments the difference between these two diameters is only 0.001 mm. This provides an ideal rotation bearing.

The coupling means according to the invention has been tested in a motion experiment, wherein the coupling

means was adjusted to a moving member with a movement similar to a natural step progression. This test showed that after 40,000 km no wear of any significance between the elements had occurred. This is clear confirmation that the coupling means according to the invention offers advantageous properties compared to the already known couplings.

## CLAIMS

1. Coupling means for a femur prosthesis comprising an adaptor element and a ball element, which elements are each provided with a blind central bore, wherein the bore of the adaptor element is suitable in shape and dimension to enable placing over a fixed stem end of a femur prosthesis and wherein the bore of the ball element is suitable in shape and dimension to enable placing over the adaptor element, and wherein, when arranged one over the other, the ball element is mounted for free rotation relative to the fixed stem end, **characterized in that** the ball element consists of a spherical ball head which transposes into a substantially cylindrical ball collar, which ball element is provided with a blind central bore which extends through the whole ball collar into a considerable part of the ball head.

2. Coupling means as claimed in claim 1, **characterized in that** the blind bore of the ball element is at least partially cylindrical, and a corresponding part of the sleeve of the adaptor element has a similar cylindrical form such that when the ball element is arranged over the adaptor element a free-rotating bearing is obtained.

3. Coupling means as claimed in claim 1 or 2, **characterized in that** the blind bore of the ball element is cylindrical.

4. Coupling means as claimed in any of the claims 1-3, **characterized in that** when arranged one over the other the adaptor element and the ball element are in continuous mutual contact only locally at one point.

5. Coupling means as claimed in any of the foregoing claims, **characterized in that** the depth of the bore of the ball element is smaller than or equal to the height of the adaptor element.

6. Coupling means as claimed in any of the foregoing claims, **characterized in that** the elements of the coupling are manufactured from a Co/Cr/Mo alloy.

7. Coupling means as claimed in any of the foregoing claims, further comprising a truncated cone-shaped stem end cap preferably manufactured from the same Co/Cr/Mo alloy.

8. Adaptor element evidently suitable for a coupling means as claimed in any of the foregoing claims 1-7, **characterized in that** the adaptor element is substantially cylindrical and provided with a central truncated cone-shaped blind bore and provided on the top side with a shaped surface.

9. Adaptor element as claimed in claim 8, **characterized in that** the shaped surface is arched and preferably spherical with one central summit.

10. Coupling assembly comprising at least one ball element as specified in claims 1-7 and a number of adaptor elements as claimed in claim 8 or 9, wherein at least two adaptor elements have a different axial length.

11. Femur prosthesis provided with a stem end on which a stem cap is provided, which stem cap is truncated cone-shaped and over which a coupling means as claimed in any of the claims 1-7 is arranged.

12. Femur prosthesis as claimed in claim 11, which prosthesis is manufactured substantially from titanium.

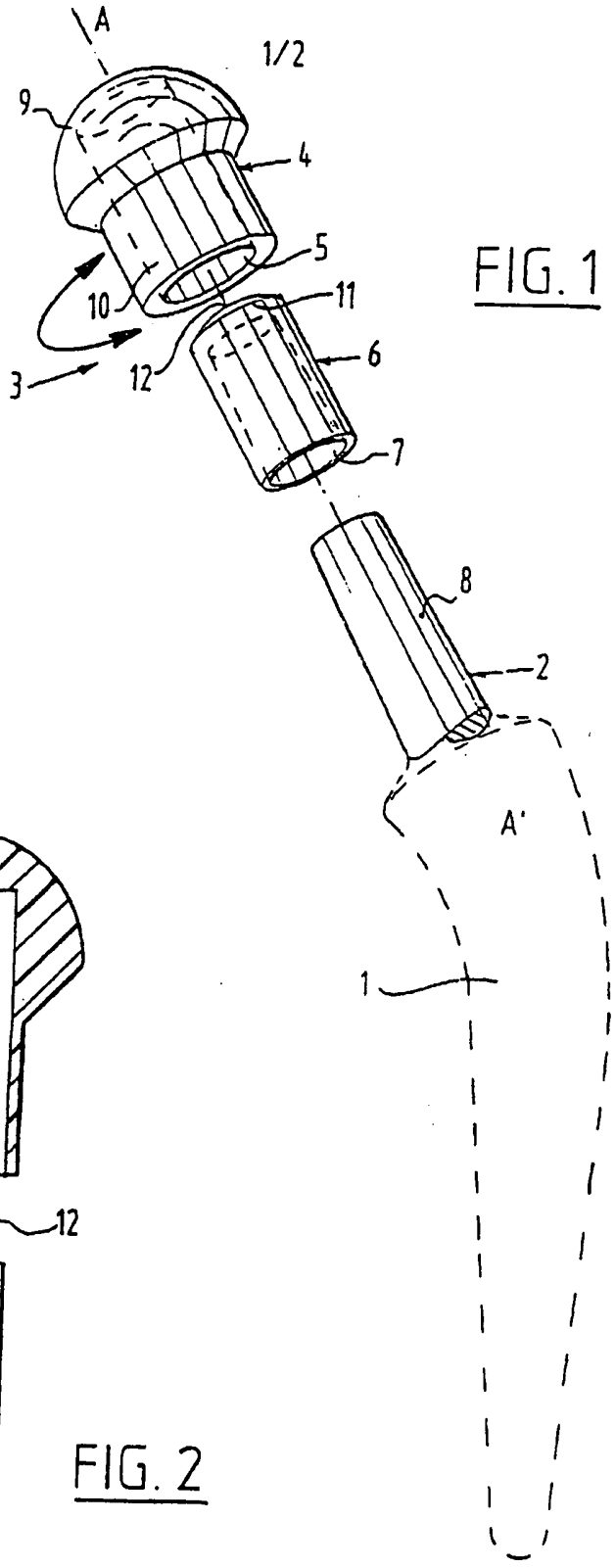


FIG. 1

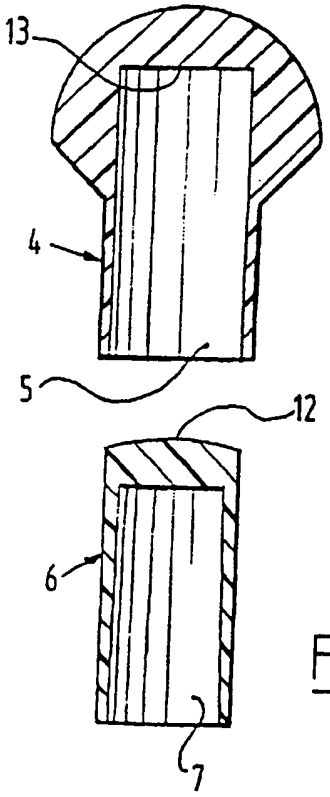


FIG. 2

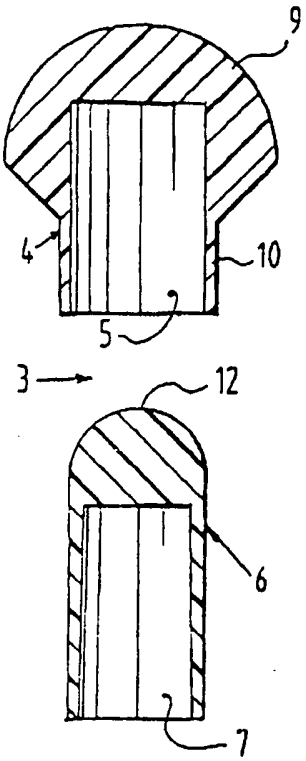


FIG. 3

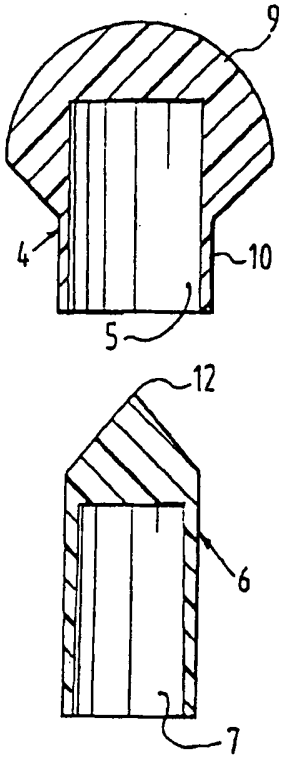


FIG. 4

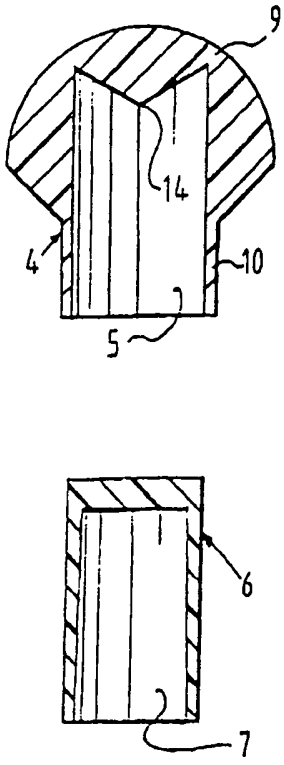


FIG. 5

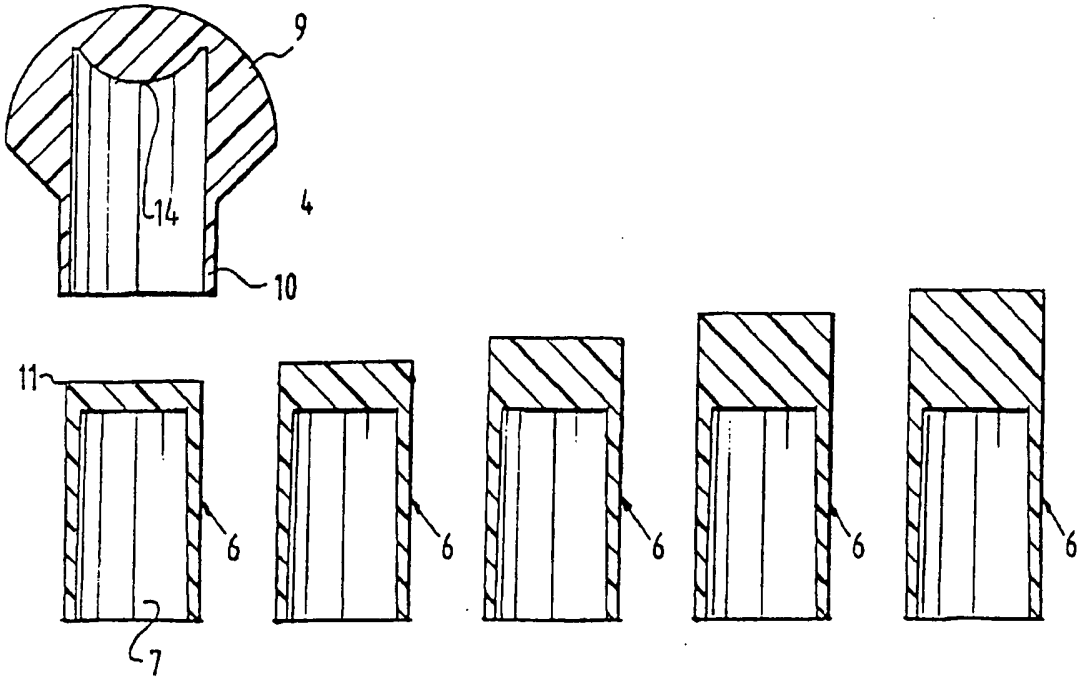


FIG. 6

# INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
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C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| Y | EP 0 147 339 A (BRUNET)<br>3 July 1985 (1985-07-03)<br>cited in the application<br>page 5, line 32 -page 6, line 1; figures 6,7 | 1-3,5 |
| Y | DE 30 33 227 A (BERENDES)<br>1 April 1982 (1982-04-01)<br>the whole document | 1-3,5 |
| A | FR 2 584 603 A (BRUNET)<br>16 January 1987 (1987-01-16)<br>the whole document | 1,2,11 |
| A | FR 2 041 767 A (ÉTABLISSEMENTS TORNIER)<br>5 February 1971 (1971-02-05)<br>the whole document | 1-3 |

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|---|---|---|
| A | US 3 658 056 A (HUGGLER)<br>25 April 1972 (1972-04-25)<br>column 3, line 11 - line 15<br>column 4, line 17 - line 21; figures 1,3 | 1,3,6 |
| A | US 5 080 679 A (PRATT)<br>14 January 1992 (1992-01-14)<br>cited in the application<br>the whole document | 2,3,6-8,<br>11,12 |
| A | US 5 156 624 A (BARNES)<br>20 October 1992 (1992-10-20)<br>the whole document | 4,9 |
| A | US 5 362 311 A (AMINO)<br>8 November 1994 (1994-11-08)<br>column 3, line 32 -column 4, line 41;<br>claims 2,5; figures 1A-5 | 6,7,<br>10-12 |
| A | FR 2 689 390 A (CÉRAMIQUES TECHNIQUES DESMARQUEST) 8 October 1993 (1993-10-08)<br>abstract; figures 2,3 | 10 |
| A | US 4 032 994 A (FREY)<br>5 July 1977 (1977-07-05) | |
| A | US 5 725 597 A (HWANG)<br>10 March 1998 (1998-03-10) | |
| A | EP 0 385 572 A (OSTEONICS CORP.)<br>5 September 1990 (1990-09-05) | |

1

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte. onal Application No
PCT/BE 00/00001

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| EP 147339 A | 03-07-1985 | FR 2558053 A | 19-07-1985 |
| DE 3033227 A | 01-04-1982 | NONE | |
| FR 2584603 A | 16-01-1987 | EP 0214065 A | 11-03-1987 |
| | | WO 9007310 A | 12-07-1990 |
| | | US 4842605 A | 27-06-1989 |
| FR 2041767 A | 05-02-1971 | NONE | |
| US 3658056 A | 25-04-1972 | AT 284329 B | |
| | | CH 490077 A | 15-05-1970 |
| | | DE 1912630 A | 30-10-1969 |
| | | ES 359759 A | 01-07-1970 |
| | | FR 2006925 A | 02-01-1970 |
| | | GB 1264857 A | 23-02-1972 |
| | | SE 363233 B | 14-01-1974 |
| US 5080679 A | 14-01-1992 | NONE | |
| US 5156624 A | 20-10-1992 | NONE | |
| US 5362311 A | 08-11-1994 | NONE | |
| FR 2689390 A | 08-10-1993 | NONE | |
| US 4032994 A | 05-07-1977 | CH 593053 A | 15-11-1977 |
| | | AT 340577 B | 27-12-1977 |
| | | AT 430975 A | 15-04-1977 |
| | | BE 842491 A | 02-12-1976 |
| | | CA 1058803 A | 24-07-1979 |
| | | DE 2524923 A | 04-11-1976 |
| | | FR 2313012 A | 31-12-1976 |
| | | GB 1495224 A | 14-12-1977 |
| | | IT 1079504 B | 13-05-1985 |
| | | JP 1106530 C | 30-07-1982 |
| | | JP 51148290 A | 20-12-1976 |
| | | JP 56050582 B | 30-11-1981 |
| | | NL 7605499 A,B, | 07-12-1976 |
| | | SE 418362 B | 25-05-1981 |
| | | SE 7606181 A | 04-12-1976 |
| US 5725597 A | 10-03-1998 | NONE | |
| EP 385572 A | 05-09-1990 | US 4921500 A | 01-05-1990 |
| | | AU 619954 B | 06-02-1992 |
| | | AU 5019190 A | 06-09-1990 |
| | | CA 2006272 A | 31-08-1990 |
| | | JP 3029651 A | 07-02-1991 |